Opening Statement of the Honorable Michael C. Burgess, M.D.
Subcommittee on Health
Hearing on "Examining FDA's Prescription Drug User Fee Program"
March 22, 2017

(As prepared for delivery)

The Subcommittee will come to order.

The Chair will recognize himself for an opening statement.

Today's hearing marks the Health Subcommittee's second opportunity to consider the reauthorization of several key FDA user fee programs. The Prescription Drug User Fee Act (PDUFA) authorized FDA to collect user fees from industry to support the approval of new drugs and biologics, and is a top priority for this Committee. It was first authorized in 1992 and, while there is always room for improvement, PDUFA has been a remarkable success, bringing safe and effective new drug products to patients in a more timely manner. Every five years since, pursuant to a process set forth in statute, Congress has reauthorized the program after reviewing recommendations from FDA, industry, patient groups, and other stakeholders.

The Committee has been reviewing the PDUFA VI agreement since December, when it was transmitted to Congress and publicly posted. As I stated at our hearing on the generic and biosimilar user fee programs earlier this month, Chairman Walden and I are committed to shepherding the user fee legislation through Committee, following regular order, and getting it to the House floor with ample time to spare.

Reauthorization of the user fee agreements every five years provides an opportunity to examine and improve upon the state of discovery, development, and delivery of medical therapies in America. For instance, the 2012 reauthorization of PDUFA in the Food and Drug Administration Safety and Innovation Act, commonly known as FDASIA, established the Breakthrough Therapy Designation. This program expedites the review and approval of promising new drugs that show early evidence of efficacy in serious, life-threatening diseases with unmet clinical need. Under this program over 165 products have been granted breakthrough

designation, which means more treatments and cures are being prioritized for patients suffering from some of the most despairing conditions. I am pleased that PDUFA VI will continue to build upon the success of the breakthrough therapy program.

A unique factor in the negotiation of PDUFA VI, was its overlap with development of the 21st Century Cures Act, a bill enacted last year after a multi-year initiative led by Representative Upton and Representative DeGette. Over the course of the 113th and 114th Congresses, members of this subcommittee worked to uncover opportunities to strengthen and streamline the process by which cures are discovered and made available to patients. The resulting law touches each step of the process through which new treatments and cures come to market. I am encouraged to see in our witnesses' testimonies that PDUFA VI will dedicate resources to complement the implementation of many of the priorities in 21st Century Cures.

In particular, I am pleased to see that FDA will formalize a structure to incorporate patient input and experience into the benefit-risk assessment of products in development. Patients have the most at stake, and they deserve to be heard. I am also encouraged to see that FDA will dedicate resources to modernize clinical trials and evidence development, including the utilization of real-world evidence and investment in biomarkers. Real-world evidence has the potential to increase efficiency and foster robust data collection and analysis. Advancing development of biomarkers has incredible promise to accelerate regulatory decision-making and to expedite the pace of clinical trials without sacrificing standards for efficacy and safety.

Numerous other provisions incorporated in the proposal for PDUFA VI reflects the top priorities of this Committee in the 21st Century Cures Act, and I want to reiterate my commitment to ensuring this reauthorization stays on track. This year will mark the fifth renewal by Congress, and it is widely agreed that PDUFA VI will provide for the timely review of new drug and biologic license applications. I thank our witnesses for being here today and I look forward to hearing more from each of you about the agreement before us today.